

***IN THE UNITED STATES PATENT AND TRADEMARK OFFICE***

Applicant: Philippe MSIKA  
Title: COSMETIC METHOD FOR PREVENTING AND/OR  
TREATING SKIN STRETCHMARKS, AND USE IN  
DERMATOLOGY  
Appl. No.: 10/808,701  
Filing Date: 3/25/2004  
Examiner: Gina C. YU  
Art Unit: 1617  
Confirmation Number: 6071

**DECLARATION UNDER 37 C.F.R. § 1.132**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I, Philippe Msika, being duly warned, hereby declare and state:

1. I understand English when it is written.
2. I was awarded a Ph.D. degree in cutaneous biology from university of Paris, France in 1986 and a Pharmacist Doctorate from university Tours, France in 1988. I am currently employed as head of Innovation, Research and Development at Laboratoires Expanscience where I have been employed since 1996. I have been conducting research and development in the fields of cosmetology and dermatology for more than 20 years.

3. I am the inventor of the invention disclosed and claimed in U.S. Patent Application No. 10/808,701 titled Cosmetic Method For Preventing And/Or Treating Skin Stretchmarks, And Use In Dermatology.

4. I have carefully reviewed U.S. Patent No. 5,444,091 to Rapaport et al. ("Rapaport") and Frei et al., International Journal of Cosmetic Science, 20, 159-173 (1998) ("Frei").

5. In my opinion, a person of ordinary skill in the art would not conclude from Rapaport that stretchmarks (striae distensae) are treated by promoting the rigidity and elasticity of the skin. Rapaport speculates that alpha hydroxy acids reduce stretch marks by (i) eliciting a hyperplastic response in the epidermis and dermis that counters the breakdown of collagen, or (ii) by stimulating the production of interfibrillary material such as glycosaminoglycans which promotes both rigidity and elasticity to the skin. See Rapaport column 4, lines 31-38. Rapaport contains no test data supporting these assertions. These proposed mechanisms in Rapaport for enhancing skin elasticity and rigidity are unsupported. Consequently, a person of ordinary skill in the art would consider these mechanisms to be speculative and unproven.

6. Frei provides no basis to infer that soya peptide increases skin firmness, elasticity, and tone. Frei does not directly state that soya peptide increases skin firmness, elasticity, and tone. Frei describes a skin equivalent (SE) model, but Frei lacks any objective measurement of skin firmness, elasticity, and tone. Frei states "the application of soya peptide ... might ... delay the in vitro process of aging." Frei, p. 171, 3d full para., last sentence (emphasis added). Frei further states "[t]his peptide is able to stimulate regeneration of metabolic activity, which may help the skin to look younger," Frei, p. 171, 4th full para., last sentence (emphasis added). The use of "might" and "may" in the sentences quoted above indicates that the authors were uncertain of these assertions.

7. Frei is equivocal about soya peptide's effect on ageing and recognizes that no definite conclusion is possible. Frei states "no conclusion could be drawn concerning the way

the soya peptide acts in this SE model.” Frei, p. 171, first full paragraph, final sentence. In my opinion, a person of ordinary skill in the art reading Frei would not conclude that soya peptide increases skin firmness, elasticity, and tone.

8. A person of ordinary skill in the art reading Frei and Rapaport would not conclude that a soya peptide would be effective for treating stretchmarks. Frei states, “In this model, the soya peptide increased the thickness of the epidermis.” See Abstract. While that effect may support anti-ageing properties, a person of ordinary skill in the art would not recognize effectiveness for treating stretchmarks.

9. Rapaport and Frei relate to nonanalogous fields. Rapaport relates to treating striae distensae, while Frei relates to treating ageing skin (see respective Abstracts of Rapaport and Frei).

10. Striae distensae and skin ageing are unrelated conditions.

11. Most of the formulas on the market dedicated to the treatment of stretchmarks do not contain anti-ageing ingredients.

12. Frei is not reasonably pertinent to the problem that Rapaport seeks to solve. Generally, the problems relating to ageing skin are not the same as the problems reflected in stretchmarks (striae distensae), as noted above.

13. A person of ordinary skill in the art would not conclude that a formulation that is effective for treating the effects of ageing in skin would also be effective in treating stretchmarks (striae distensae).

14. I arrived at the preceding opinions in part because skin ageing and striae distensae have different etiologies, and the physicochemical attributes of ageing skin are different from those for stretchmarks.

15. Stretchmarks appear in 50 to 70 % of the pregnant women, whereas ageing is not limited to the pregnant population.

16. The localization of the two conditions skin ageing and striae distensae differs: Stretchmarks appear on the hip, the breasts, and the buttocks, while ageing appears on the entire skin, but especially on the face and the hands.

17. The appearance of the two conditions differs. Stretchmarks appear as a red or white deep scar which never disappear, while wrinkles have a different appearance.

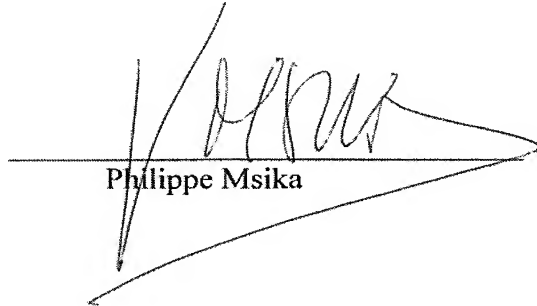
18. The risk factors of the two conditions differ. For stretchmarks, risk factors include heredity, age (young women), height and weight. Skin ageing does not concern young people, and body weight is not a parameter.

19. The etiologies of skin ageing and striae distensae differ greatly. For striae distensae, biomechanical distension and hormonal (cortisol) impregnation plus inflammation which modify fibroblast phenotype (limitation of the production of collagen and elastin, modification of the type of protein secreted, and alteration of the structure) versus, for skin ageing, a chronological action upregulated by the sun or menopause (no inflammation at all in the natural and the hormonal ageing, no modification of the phenotype of cells, a destruction of the protein).

20. Due to the complicated etiology, a product that stimulates collagen synthesis and elasticity of the skin is not sufficient to prevent or treat stretchmarks.

21. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent resulting therefrom.

08/11/12  
Date

  
Philippe Msika